K080940

510(k) SUMMARY
Tokuyama Dental Corporation
ESTELITE SIGMA QUICK

JUN 19 2008

Name of Device

Trade or Proprietary Name:	ESTELITE SIGMA QUICK
Common Name:	tooth shade resin material
Classification Name:	material, tooth shade, resin
Product Code:	EBF

Preparation Date

March 28, 2008

510(k) Sponsor

Tokuyama Dental Corporation
38-9 Taitou 1-chome, Taitou-ku
Tokyo
110-0016
Japan

510(k) Sponsor Contact

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
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Intended Use

ESTELITE SIGMA QUICK is is a light cured, radiopaque, submicron-filled composite resin for use in anterior and posterior restorations and is indicated for all carious classes.

Technological Characteristics and Substantial Equivalence

The chemical structure of ESTELITE SIGMA QUICK is nearly identical to Tokuyama's own ESTELITE SIGMA (a modification of K#980051) and ESTELITE FLOW QUICK (K#051808). ESTELITE SIGMA QUICK is formulated to shorten the curing time of the resin material compared to ESTELITE SIGMA.

The ESTELITE SIGMA QUICK is substantially equivalent, for purposes of FDA market authorization, to Tokuyama's own ESTELITE SIGMA (K#980051 as modified) and ESTELITE FLOW QUICK (K#051808). Although the ESTELITE SIGMA QUICK has a slightly different chemical formulation than either product, these differences do not raise new questions of safety or effectiveness, as discussed below.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2008

Tokuyama Dental Corporation
C/O Mr. Keith A. Barritt, Esq.
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
Washington, DC 20005

Re: K080940
Trade/Device Name: ESTELITE SIGMA QUICK
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: April 2, 2008
Received: April 4, 2008

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080940

Device Name: Estelite Sigma Quick

Indications for Use:

For use as a tooth shade resin in dental procedures.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080940